2018

This template to be completed by all Principle Investigators



Biosafety Plan

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| **General Instructions** Complete each section of the biosafety plan template. The biosafety plan should describe the equivalent risk group and containment level requirements for the organisms, biological materials, or biohazardous materials to be used. The biosafety plan should address all organism(s), biological materials and biohazardous materials under the biosafety permit. Do not create a separate biosafety plan for each type of permitted material.Refer to the resources included in each section of the template for further information and to assist in the development of the biosafety plan. For assistance preparing a biosafety plan, contact the Biosafety Officer, Safety Services.  |

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# Biosafety Permit Information

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| Permit Holder Name: |
| Permit Holder Telephone Number: |
| Email: |
| Laboratory Room Number: |
| Laboratory Contact Name: |
| Laboratory Contact Telephone Number: |
| Email: |

# Nature of Research Work

**Instructions:**

Provide a brief description of the nature of the work that will be performed in the research protocol and under your biosafety permit. Reference any relevant documents.

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# Biological Risk Assessment

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| **Instructions:** The critical step in developing a biosafety plan is to determine the risk group and containment level for the organism, biological material or biohazardous material that is to be used. Listed below, are a number of resources that provide risk group and containment level information for a wide range of organisms and biohazardous materials. * *Human Pathogens and Toxins Act, Schedule 1-5*

 (<http://www.phac-aspc.gc.ca/lab-bio/regul/index-eng.php>).* *Pathogen Safety Data Sheets and Risk Assessment,* PHAC*,*

 (<http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php>).* *Disease Agent Information,* CFIA*,*

 (<http://www.inspection.gc.ca/english/sci/bio/anima/disemala/disemalae.shtml>).* *Risk Group Classification for Infectious Agents,* American Biological Safety Association,

 (<http://www.absa.org/riskgroups/index.html>).* *National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules,* National Institutes of Health (NIH),

 (<http://oba.od.nih.gov/oba/rac/Guidelines/APPENDIX_B.htm#_Toc7238342>).* *Biosafety in Microbiological and Biomedical Laboratories*, Centers for Disease Control, National Institutes of Health,

 (<http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf>).If the risk group and containment level of the organism, biological material or biohazardous material has been determined by an external source(s) (e.g. PHAC, CFIA, NIH), reference the source and available technical information.If the organism, biological material or biohazardous material risk group and containment level is not already determined, a biological risk group and containment level assessment must be performed. The [*Biological Risk Group and Containment Level Assessment* *Template*](http://www.uleth.ca/risk-and-safety-services/sites/risk-and-safety-services/files/Biological%20Risk%20Group%20and%20Containment%20Level%20Assessment%20Template.pdf) is to be used to determine the appropriate risk group and corresponding containment level of each organism, biological material or biohazardous material. Include a copy of each biological risk group and containment level assessment for each permitted material as an appendix to the biosafety plan.Include or reference available technical information including Pathogen Safety Data Sheets (PSDS), technical data sheets and/or related journal articles for each organism, biological material or biohazardous material.Prepare an inventory of the organisms, biological materials and biohazardous materials that will be used under the biosafety permit (see Table 1).***.*** |

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**Table 1: Inventory of organisms, biological materials and biohazardous materials.**

| **Name of Biological Material** | **Purpose or Use** | **Quantity/Concentration** | **Risk Group\*****(1, 2, 3)** | **Containment Level\*****(1, 2, 3)** | **References\*\*** |
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\*The identified risk group and containment level as specified by external sources, or as determined from a biological risk and containment level assessment.

\*\*Indicate the reference for the categorization of the risk group and containment level (e.g. risk assessment performed by researcher, PHAC, CFIA).

# Work Locations

**Instructions:**

Identify the locations where the organism(s), biological materials and biohazardous materials will be used and stored. Include a description of the facility and safety equipment (e.g. biosafety cabinets, autoclaves) that will be employed. Complete Table 2.

Work and storage locations must meet containment level requirements as determined from the risk assessment information for each organism, biological material or biohazardous material. The following resources provide details of facility design and operational requirements based on the identified containment level.

• *Canadian Biosafety Standard* (CBS), 2nd Edition, 2015

(<http://canadianbiosafetystandards.collaboration.gc.ca>)

• *Canadian Biosafety Handbook* (CBH), 2nd Edition, 2015.

(<http://canadianbiosafetystandards.collaboration.gc.ca>)

•Containment Standards for Facilities Handling Plant Pests, CFIA,

(<http://www.inspection.gc.ca/english/sci/bio/plaveg/placone.pdf>).

•Containment Standards for Facilities Handling Aquatic Animal Pathogens, CFIA,

(<http://www.inspection.gc.ca/english/sci/bio/anima/aqu/csfncie.pdf>).

•Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control, National Institutes of Health,

(<http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf>).

The Biosafety Officer is available to assist with ensuring facilities meet containment level standards.

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Table 2: Biosafety permit work and storage locations.

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| **Location** | **Purpose\*** | **Nature of Work** | **Safety Equipment\*\*** | **Containment Level\*\*\*** |
| **Type and Model** | **Serial Number** |
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\*Provide the purpose or use of the location which could include, work, diagnostic, decontamination, storage, etc..

\*\*Safety equipment includes but is not limited to, biosafety cabinets, fume hoods, hand washing sinks, emergency eyewash and shower equipment.

\*\*\*Depending on the required containment level, there will be specific facility location, access, design and construction, air handling, containment perimeter, laboratory services, and safety equipment. Refer to the *Canadian Biosafety Standard* (CBS), 2nd Edition, 2015 and • *Canadian Biosafety Handbook* (CBH), 2nd Edition, 2015.

# Health and Safety Hazards

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| **Instructions:** To determine health and safety risks, including risks of exposure to pathogens and toxins, one must consider not only the types of biohazardous materials being used but also the proposed manipulations and handling of these materials under the research protocol or activity.For each organism, biological material or biohazardous material, or class of materials (with similar risk characteristics), complete the following sections under Health and Safety Hazards.* Name of biological material, its risk group and required containment level.
* Identify each procedure/technique that will be carried out under the permit. Include equipment and tools that will be used.
* Identify the exposure hazards (risk groups 2) and any other health and safety hazards (e.g. chemical, radiological and physical) that exist for each procedure/technique.

Consider the key steps in each procedure/technique when identifying health and safety hazards.The following procedures commonly used in the laboratory may create a risk of exposure to organisms or biohazardous material.* The use of needles or other sharps.(i.e. injections, phlebotomy, dissections)
* Handling human or animal blood, fluid, or tissue ;
* Pipetting, mixing, or vortexing of pathogens and/or biohazardous material
* Pipetting, mixing, or vortexing pathogens and/or biohazardous material;
* Centrifuging pathogens or biohazardous material.
* Preparing or handling human, animal or biohazardous material cell cultures;
* Handling contaminated sharps or other contaminated waste; and
* Cleaning spills of human or animal blood or other body fluids or biological hazardous material.
* Identify the possible diseases or adverse health effects associated with exposure to the organism or biohazardous material (risk groups 2). Include the signs and symptoms of known diseases.
* Identify the exposure routes for the organism or biohazardous material (inhalation, ingestion, skin contact, injection).
* Provide a description of known allergies that could develop from working with the organism(s) (risk groups 1, 2). Include symptoms of the allergies.

**Resources*** Canadian Biosafety Standard (CBS), 2nd Edition, 2015

 (<http://canadianbiosafetystandards.collaboration.gc.ca>) * Containment Standards for Facilities Handling Plan Pests, CFIA,

(<http://www.inspection.gc.ca/english/sci/bio/plaveg/placone.pdf>). * Containment Standards for Facilities Handling Aquatic Animal Pathogens, CFIA,

(<http://www.inspection.gc.ca/english/sci/bio/anima/aqu/csfncie.pdf>). * Laboratory Biosafety Manual, World Health Organization,

(<http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/>) . * Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control, National Institutes of Health, (<http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf>).
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# Health and Safety Control Measures

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| **Instructions:** Describe the safety measures that are in place to protect workers from exposure to biohazards, or other identified hazards. Safety measures should be commensurate with the identified hazards and may include:* Engineering controls (i.e. facility design, biosafety cabinets, fume hoods, chemical storage);
* Administrative controls: Work procedures, SOP, guidelines, code of practice;
* Personal protective equipment (PPE);
* Medical surveillance (medical examination, vaccinations if available and recommended, serum screening);

In this section, also outline the methods and SOP to be used for the disinfection and decontamination of work areas, equipment and materials.**Resources**Following are resources that provide information on biosafety.* *Canadian Biosafety Standard (CBS), 2nd Edition, 2015*

(<http://canadianbiosafetystandards.collaboration.gc.ca>)* *Containment Standards for Facilities Handling Plan Pests*, CFIA,

(<http://www.inspection.gc.ca/english/sci/bio/plaveg/placone.pdf>).* *Containment Standards for Facilities Handling Aquatic Animal Pathogens*, CFIA,

(<http://www.inspection.gc.ca/english/sci/bio/anima/aqu/csfncie.pdf>).* *Laboratory Biosafety Manual*, World Health Organization,

(<http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/>).* *Biosafety in Microbiological and Biomedical Laboratories*, Centers for Disease Control, National Institutes of Health,

(<http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf>). |

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# Potential for Dual Use Research

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| * A key component to the hazard assessment is the identification of dual-use potential which all researchers are required to complete.
* Dual use potential is commonplace in life sciences research because reagents, experimental approaches and derived knowledge often have the potential to be misused and misapplied to obtain nefarious outcomes.
* A dual-use risk assessment, if done appropriately, should contribute to effective biosecurity oversight.

**Instructions:*** Faculty/Researchers will use the Public Health Agency of Canada flow chart below to assist with proper identification of dual-use.
* When research with dual-use potential is identified, it is important to assess the risk associated with the research. The general concepts of a risk assessment take into consideration the hazards identified, the likelihood that the hazard will occur, and the magnitude of the foreseeable consequences. A proper risk assessment should guide the selection of appropriate mitigation strategies to protect the research materials, tools, and information against potential theft, misuse, diversion, or intentional release.
* When researchers apply for amendments or renew biosafety permits, they will be required to revisit the chart and indicate if the RG2 material or procedures would pose a potential dual use. This will complement the hazard identification process which is expected to occur when a new material is acquired or a new teaching or research program is initiated.
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# Biosecurity

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| **Instructions:** The permit holder shall implement and maintain biosecurity measures commensurate with the identified risk group and containment level of the biohazardous materials under the biosafety permit and legislative requirements. This includes, but is not limited to:* Physical protection of the permitted facility to minimize unauthorized access to facilities, laboratories and storage areas;
* Personnel authorization and clearance of authorized workers to work in the facility; and
* Inventory management of organisms, biological materials, and biohazardous materials used and stored under the biosafety permit.

Incident reporting, response, and investigation into suspected criminal activity including the loss or suspected theft of organisms, biological materials, or biohazardous materials is addressed under Section 10, Emergency Response.In the section, provide a description of the biosecurity measures for the facility being permitted. The minimum requirements for biosecurity for risk group 1 and 2 are:* Controlled access to the facility. Doors to facilities should be kept closed at all times. Access doors to the facility should be lockable.
* Access to the facility should be limited to authorized workers. Visitors must be accompanied by an authorized worker.
* An up-to-date inventory of organisms, biological materials, and biohazardous materials used and stored under the biosafety permit.

**Resources**Following are resources that provide information on biosecurity.* *Canadian Biosafety Standard (CBS), 2nd Edition, 2015*

(<http://canadianbiosafetystandards.collaboration.gc.ca>)* *Containment Standards for Facilities Handling Plan Pests*, CFIA,

(<http://www.inspection.gc.ca/english/sci/bio/plaveg/placone.pdf>).* *Containment Standards for Facilities Handling Aquatic Animal Pathogens*, CFIA,

(<http://www.inspection.gc.ca/english/sci/bio/anima/aqu/csfncie.pdf>).* *Laboratory Biosafety Manual*, World Health Organization,

(<http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/>).* *Biosafety in Microbiological and Biomedical Laboratories*, Centers for Disease Control, National Institutes of Health,

(<http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf>). |

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# Hazardous Waste Disposal

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| **Instructions:** Provide a description of the disposal of hazardous and non-hazardous biological waste and other hazardous waste (e.g. chemical, radiological) that may be generated during work activities under the biosafety permit. The method of disposal for each type of hazardous waste (e.g. chemical disinfection, autoclave, service provider) should be included in the description. |

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# Emergency Response

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| **Instructions:** Provide a description of the measures to be taken in the event of an emergency. Procedures should be developed to respond to the following types of incidents:* Medical emergencies which include injuries and confirmed or suspected illness from exposure to pathogens or biohazardous material
* Spills of hazardous materials;
* Containment equipment failures;
* Loss or theft of hazardous materials;
* Power outages;
* Fire; or
* Other types of incidents related to the work activities (e.g. an uncontrolled release to the environment).
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